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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VIFOR (INTERNATIONAL) AG and AMERICAN REGENT, INC., Plaintiffs, v. MYLAN LABORATORIES LTD., Defendant.	Civil Action No. 20-1647 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Vifor (International) AG ("Vifor") and American Regent, Inc. ("American Regent") (collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Mylan Laboratories Ltd. ("Mylan"). This action relates to Abbreviated New Drug Application ("ANDA") No. 212572, filed by Mylan with the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of Plaintiffs' Injectafer®, ferric carboxymaltose injection (750 mg/15 ml) ("Mylan's ANDA

Product") prior to the expiration of United States Patent No. 10,519,252 ("the '252 patent"). The '252 patent is listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for Injectafer®.

THE PARTIES

2. Plaintiff Vifor is a company organized and existing under the laws of Switzerland, having a principal place of business at Rechenstraβe 37, CH-9001, St. Gallen, Switzerland.

3. Vifor is engaged in the business of creating, developing, and bringing to market revolutionary drug products, including treatments for iron deficiency anemia.

4. Plaintiff American Regent is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967. American Regent was formerly known as Luitpold Pharmaceuticals, Inc., until January 2, 2019, when its New York Certificate of Incorporation was amended to change the name of the corporation to American Regent, Inc. American Regent is a subsidiary of Daiichi Sankyo, Inc, ("Daiichi Sankyo") which is located at 211 Mt. Airy Road, Basking Ridge, New Jersey 07920.

5. Vifor and American Regent developed Injectafer®. American Regent licenses Injectafer® from Vifor, and American Regent has contracted with Daiichi Sankyo Inc., through a Marketing Services Agreement, to market Injectafer® in this judicial district and throughout the United States.

6. On information and belief, Defendant Mylan is a company organized and existing under the laws of India, with a principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India.

7. On information and belief, Mylan is a generic pharmaceutical company that develops and manufactures generic pharmaceutical products that are marketed and sold throughout the United States.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, et seq., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. On information and belief, this Court has personal jurisdiction over Mylan, under the New Jersey state long arm statute and consistent with due process of law, because it regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, demonstrating that Mylan has systemic and continuous contacts with this judicial district.

10. On information and belief, Mylan purposefully has conducted and continues to conduct business in this judicial district by manufacturing, importing, marketing, and distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates, throughout the United States, including in this judicial district.

11. On information and belief, Mylan is subject to personal jurisdiction in this judicial district through its pursuit of regulatory approval for Mylan's ANDA Product for the commercial manufacture, use, and/or sale of Mylan's ANDA Product, if approved, in this judicial district and to residents of this judicial district. Through at least these activities, Mylan has purposely availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district.

12. On information and belief, Mylan has been, and continues to be, wholly responsible for the drafting, submission, request for approval, and maintenance of ANDA No. 212572. Mylan's "Notice of Paragraph IV Certification" dated May 7, 2019 ("Mylan's Notice Letter") identified "Mylan Laboratories Ltd." as the entity which submitted ANDA No. 212572 to the FDA.

13. On information and belief, if ANDA No. 212572 is approved, Mylan will import, market, distribute, offer for sale, and/or sell Mylan's ANDA Product, either by itself or through its parent corporation, subsidiaries and/or affiliates, in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Mylan's ANDA Product in the state of New Jersey.

14. On information and belief, if ANDA No. 212572 is approved, Mylan's ANDA Product will be marketed, distributed, offered for sale, and/or sold in New Jersey; prescribed by physicians practicing in New Jersey; administered by healthcare providers located within New Jersey; and/or used by patients in New Jersey, all of which will have a substantial effect on New Jersey.

15. If ANDA No. 212572 is approved, Vifor and American Regent will be harmed by the marketing, distribution, offer for sale, and/or sale of Mylan's ANDA Product, including in New Jersey.

16. On information and belief, Mylan has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this judicial district. *See, e.g.*, *AstraZeneca AB et al. v. Mylan Pharmaceuticals Inc. et al.*, Civil Action No. 13-04022 (D.N.J. Apr. 28, 2014), ECF No. 51 at 30. In fact, Mylan has filed counterclaims in this judicial district in another Hatch-Waxman litigation involving the same parties arising from Mylan's filing of the

same ANDA, ANDA No. 212572. *Vifor (International) AG, et al. v. Mylan Laboratories, Ltd.*, Civil Action No. 19-13955, ECF No. 16 at 19-25.

17. Alternatively, this Court has personal jurisdiction over Mylan pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Mylan is a foreign entity, Plaintiffs' claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, Mylan has systemic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

18. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) for at least the reason that Mylan is a foreign corporation not residing in any United States district and may be sued in any judicial district that has personal jurisdiction, including this judicial district. Mylan has previously admitted, that as a foreign entity, venue is proper against it in New Jersey. *Valeant Pharm. N. Am. LLC v. Mylan Pharm. Inc.*, Civil Action No. 18-14305, ECF No. 21 at 6 n.1 ("MLL [Mylan Laboratories Ltd.] is incorporated in India. D.I. 1 ¶ 6. Under *In re HTC Corp*., 889 F. 3d 1349 (Fed. Cir. 2018), venue for foreign corporations is governed by the general venue statute, which provides that 'a defendant not resident in the United States may be sued in any judicial district.' 28 U.S.C. § 1391(c)(3). The Mylan Defendants do not dispute that venue is proper over MLL as a foreign corporation in any judicial district ….").

19. On information and belief, Mylan has committed acts of infringement under the meaning of 28 U.S.C. § 1400(b) by submitting ANDA No. 212572 to the FDA, by taking steps

indicating its intent to market Mylan's ANDA Product in New Jersey, and by the acts that it non-speculatively intends to take in New Jersey if its ANDA receives final FDA approval.

20. On information and belief, Mylan has taken steps in New Jersey, including preparing ANDA No. 212572 and communicating with the FDA regarding ANDA No. 212572, that indicate its intent to market Mylan's ANDA product. As set forth above, on information and belief, if ANDA No. 212572 is approved, Mylan intends to commit acts of patent infringement in New Jersey, including marketing, distributing, offering for sale, and/or selling Mylan's ANDA Product.

PATENT-IN-SUIT

21. The U.S. Patent and Trademark Office ("PTO") issued the '252 patent, entitled "Aqueous Iron Carbohydrate Complexes, Their Production and Medicaments Containing Them," on December 21, 2019 to inventors Peter Geisser, Erik Philipp, and Walter Richle. Vifor is the assignee of the '252 patent and has the right to enforce it. The '252 patent expires on October 20, 2023. The '252 patent claims, *inter alia*, iron carbohydrate complexes, compositions comprising said complexes, and methods of treating iron deficiency anemia by administering the claimed iron carbohydrate complexes. A true and correct copy of the '252 patent is attached hereto as **Exhibit A**.

22. American Regent is the owner of NDA No. 203565 for Injectafer® (ferric carboxymaltose) which the FDA approved on July 25, 2013. The Orange Book lists the NDA holder as American Regent, Inc., in accordance with the name change from Luitpold Pharmaceuticals, Inc. to American Regent, Inc., effective January 2, 2019. In conjunction with NDA No. 203565, American Regent listed with the FDA U.S. Patent Nos. 7,612,109 ("the '109 patent"); 7,754,702 ("the '702 patent"); 8,895,612 ("the '612 patent"); and 9,376,505 ("the '505

patent"). American Regent subsequently timely listed the '252 patent with the FDA after that patent issued. All five patents—the '109, '702, '612, '505, '252 patents—are currently listed in the Orange Book for Injectafer®. The '252 patent expires on or before the other Orange Book listed patents for Injectafer®.

MYLAN'S INFRINGING ANDA SUBMISSION

23. Plaintiffs reallege, and incorporate in full herein, each of the preceding paragraphs 1-22.

24. Plaintiffs received a letter from Mylan dated May 7, 2019, purporting to be a Notice of Paragraph IV Certification for ANDA No. 212572 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii).

25. Mylan's Notice Letter states that "Mylan Laboratories Ltd." has submitted to the FDA ANDA No. 212572 seeking to engage in the commercial manufacture, use, and/or sale of Mylan's ANDA Product before the expiration of the '109, '702, '612, and '505 patents. On information and belief, Mylan also seeks approval to engage in the commercial manufacture, use, and/or sale of Mylan's ANDA Product before the expiration of the '252 patent. Mylan's Notice Letter did not identify any other entity that is involved in the preparation, filing, and/or maintenance of ANDA No. 212572.

26. Mylan has made, and continues to make, substantial preparation in the United States to manufacture, use, import, offer to sell, and/or sell Mylan's ANDA Product, either by itself or through its parent corporation, subsidiaries and/or affiliates, before the expiration of the '252 patent.

27. By filing ANDA No. 212572, and as indicated in Mylan's Notice Letter, Mylan has represented to the FDA that Mylan's ANDA Product has the same active ingredient as

Injectafer®, has the same dosage form and strength as Injectafer®, and is bioequivalent to Injectafer®.

28. On information and belief, Mylan is seeking approval to market Mylan's ANDA Product for the same approved indications as Injectafer®.

29. Plaintiffs filed a complaint for patent infringement of the '109, '702, '612, and '505 patents before the expiration of the forty-five days from the date Plaintiffs received Mylan's Notice Letter. *Vifor (International) AG, et al. v. Mylan Laboratories, Ltd.*, Civil Action No. 19-13955, ECF No. 1 (D.N.J. June 18, 2019). The '252 patent had not issued at the time.

30. On December 31, 2019, the U.S. Patent and Trademark Office issued the '252 patent. Plaintiffs timely notified the FDA on January 17, 2020, and the '252 patent was listed in the Orange Book for Injectafer®.

31. On January 24, 2020, after the '252 patent was listed in the Orange Book, Plaintiffs' outside counsel notified Mylan's outside counsel of the listing.

COUNT I (INFRINGEMENT OF THE '252 PATENT UNDER § 271(e)(2)(A))

32. Plaintiffs reallege, and incorporate in full herein, each of the preceding paragraphs 1-31.

33. Under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim of the '252 patent, including for example claims 1, 13, and 18, by submitting, or causing to be submitted to the FDA, ANDA No. 212572 seeking approval to engage in the commercial manufacture, use or sale of Mylan's ANDA Product before the expiration date of the '252 patent. On information and belief, the product described in ANDA No. 212572 would infringe, either literally or under the doctrine of equivalents, at least one claim, including for example claims 1, 13, and 18 of the '252 patent under 35 U.S.C. § 271(e)(2)(A).

34. On information and belief, the fact that Mylan has represented to the FDA that Mylan's ANDA Product is bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, Mylan is required to substantially copy the FDA-approved Injectafer® labeling, Mylan's ANDA Product comprises an aqueous solution of an iron (III) carboxymaltodextrin complex, wherein the iron (III) carboxymaltodextrin is derived from the oxidation of maltodextrin and has a weight average molecular weight of 80 to 400 kilodaltons, and will be used in a method of treating an iron deficiency condition, and satisfies all of the limitations of at least claims 1, 13, and 18 of the '252 patent.

35. On information and belief, upon FDA approval of Mylan's ANDA Product, Mylan will infringe at least one claim, including for example claims 1 and 13 of the '252 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents, by making, using, importing, offering to sell, and/or selling Mylan's ANDA Product in the United States.

36. On information and belief, upon FDA approval of Mylan's ANDA Product, Mylan will induce and/or contribute to the infringement of one or more claims, including for example claims 1, 13, and 18 of the '252 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

37. Mylan has knowledge of the '252 patent and has filed ANDA No. 212572 seeking authorization to engage in the commercial manufacture, use or sale of Mylan's ANDA Product in the United States. On information and belief, if the FDA approves ANDA No. 212572, healthcare providers and/or patients will directly infringe under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, at least one claim of the '252 patent, including for

example claims 1, 13, and 18, by the use Mylan's ANDA Product according to Mylan's provided instructions and/or label.

38. On information and belief, Mylan knows and intends that healthcare providers and/or patients will use Mylan's ANDA Product according to Mylan's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '252 patent with the requisite intent under 35 U.S.C. § 271(b).

39. Upon information and belief, upon approval, Mylan will take active steps to encourage the use of Mylan's ANDA Product by healthcare providers and/or patients with the knowledge and intent that it will be used by healthcare providers and/or patients in a manner that infringes at least one claim, including for example claims 1, 13, and 18 of the '252 patent for the pecuniary benefit of Mylan. Upon information and belief, Mylan will thus induce infringement of at least one claim of the '252 patent with the requisite intent under 35 U.S.C. § 271(b).

40. Upon information and belief, if the FDA approves ANDA No. 212572, Mylan's ANDA Product will be specifically labeled for use in practicing at least one claim of the '252 patent, wherein Mylan's ANDA Product is a material part of the claimed invention, wherein Mylan knows and intends that healthcare providers and/or patients will use Mylan's ANDA Product in a manner that infringes at least one claim, including for example claims 1, 13, and 18 of the '252 patent, and wherein Mylan's ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, Mylan will thus contribute to the infringement of at least one claim of the '252 patent under 35 U.S.C. § 271(c).

41. Upon information and belief, Mylan's actions relating to Mylan's ANDA No. 212572 complained of herein were done by and for the benefit of Mylan.

42. If Mylan's marketing and sale of Mylan 's ANDA Product prior to the expiration of the '252 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II (DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '252 PATENT)

43. Plaintiffs reallege, and incorporate in full herein, each of the preceding paragraphs 1-42.

44. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

45. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

46. Mylan became aware of the '252 patent at least no later than January 24, 2020, when Plaintiffs sent a letter to Mylan regarding the timely listing of the '252 patent in the Orange Book for Injectafer®.

47. On information and belief, Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Mylan's ANDA Product prior to the expiration of the '252 patent, including Mylan's filing of ANDA No. 212572.

48. Mylan's actions, including, but not limited to, the development of Mylan's ANDA Product, the content of and instructions in Mylan's proposed label, the filing of ANDA No. 212572, and engaging in litigation to manufacture, offer to sell, sell and/or import Mylan's ANDA Product prior to patent expiry, indicate a refusal to change the course of its action and

reliably predict that Mylan will continue to make substantial preparations to manufacture, sell, offer to sell, and/or import Mylan's ANDA Product.

49. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan's ANDA Product prior to the expiration of the '252 patent will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '252 patent.

50. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan ANDA Product prior to the expiration of the '252 patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '252 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

1. A judgment that the claims of the '252 patent are not invalid or unenforceable, and are infringed by Mylan's submission of ANDA No. 212572 under 35 U.S.C. §271(e)(2)(A), and that Mylan's making, using, offering to sell, or selling in the United States, or importing into the United States, Mylan's ANDA Product will infringe the '252 patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval by the FDA of ANDA No. 212572 shall be a date that is not earlier than the expiration date of the '252 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

3. An order permanently enjoining Mylan, its parent corporation, affiliates, subsidiaries, and each of its officers, agents, servants, employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing

into the United States Mylan's ANDA Product until after the expiration date of the '252 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

4. Damages or other monetary relief to Plaintiffs if Mylan engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Mylan's ANDA Product prior to the expiration date of the '252 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs is or becomes entitled, in accordance with 35 U.S.C. § 271(e)(4)(C);

5. A declaration issued under 28 U.S.C. § 2201 that if Mylan, its parent corporation, affiliates, subsidiaries, and each of its officers, agents, servants, employees, and those acting or attempting to act in privity or concert with them, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '252 patent, it will constitute an act of infringement of the '252 patent; and

6. Such further and additional relief as this Court deems just and proper, including any appropriate relief under 35 U.S.C. § 285.

Dated: February 14, 2020
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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